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510(k) Summary Statement
For the Lyra™Surgical Laser System & Accessories

General Information

A. Trade Name

Lyra™ Series Surgical Laser System & Accessories

B. Common Name

Laser Instrument, Surgical, Powered

C. Establishment Registration Number

2937094

D. Manufacturer's Identification

Laserscope
3070 Orchard Drive
San Jose, CA 95134-2011
(404) 943-0636
(503) 961-1688 FAX

Official Correspondent
Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs

E. Device Classification

The Lyra™ Series Surgical Laser System & Accessories has been specifically classified as a Class II medical device by the OB/GYN, General Plastic Surgery, and ENT Device Advisory Panels.

F. Performance Standards

The Lyra™ Series Surgical Laser System & Accessories conforms with federal regulations and the performance standards 21 CFR 1040.10 and 1040.11 for medical laser systems.

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G. Predicate Devices:

- Family of Altus Medical CoolGlide™ Aesthetic Lasers
- EpiLight® Manufactured by ESC Medical Systems
- PhotoDerm® Manufactured by ESC Medical Systems
- Laserscope Lyra™ Surgical Laser System
- Cynosure Apogee-TKS Dermatological Laser
- Palomar LightSheer™ Long Pulse Ruby Laser
- LightSheer™ Pulsed Diode Array Laser

H. Product Description:

The Laserscope Lyra™ Surgical Laser System & Accessories is comprised of the following main components:

- A Laser Console
- A Fiber Port (for Delivery Devices)
- Control and Display Panels
- Operating Software
- Footswitch and Handswitch Delivery Controls
- A variety of Delivery Devices and Accessories
- A Cooling Sub-system

I. Indications For Use

The Lyra™ Laser System & Accessories is used for the removal and lightening of unwanted hair. It is also intended to effect stable long-term, or permanent hair reduction in skin types I - VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.

J. Rationale for Substantial Equivalence:

- The Laserscope Lyra™ Surgical Laser System &, Accessories share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to: the Family of Altus Medical CoolGlide™ Aesthetic Lasers; EpiLight® manufactured by ESC Medical Systems; PhotoDerm® manufactured by ESC Medical; Cynosure Apogee-TKS Dermatological Laser; Palomar LightSheer™ Long Pulse Ruby Laser; and, LightSheer™ Pulsed Diode Array Laser. Details are provided in the Substantial Equivalence Section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. Paul Hardiman
Manager, Regulatory Affairs/Clinical Affairs
Laserscope
3052 Orchard Drive
San Jose, California 95134

Re: K010834
Trade/Device Name: Lyra™ Series Surgical Laser System & Accessories
Regulation Number: 874.4810
Regulatory Class: II
Product Code: GEX
Dated: March 15, 2001
Received: March 20, 2001

Dear Mr. Hardiman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K010834

Device Name: LYRA ™ SERIES SURGICAL LASER SYSTEM & ACCESSORIES

Indications for Use:

The Lyra™ Laser System & Accessories is used for the removal and lightening of unwanted hair. It is also intended to effect stable long-term, or permanent hair reduction in skin types I – VI through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as a long-term, stable, reduction in the number of hairs re-growing after a treatment regimen.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ or Over –The-Counter-Use

(per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010834